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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,999	03/01/2002	Takashi Kawasuji	2002_0288A	5732

513 7590 04/09/2007
WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER

EPPERSON, JON D

ART UNIT	PAPER NUMBER
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1639

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/069,999	KAWASUJI ET AL.	
	Examiner	Art Unit	
	Jon D. Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-14 and 17-23 is/are pending in the application.
- 4a) Of the above claim(s) 17-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/15/04; 3/26/02; 3/1/02</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination (RCE)

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/2/06 has been entered. Claims 1-23 were pending. Applicants canceled claims 1-6, 15, 16, and 24. In addition, Applicants amended claims 7, 8, 17, 18, 19 and 20. No claims were added. Therefore, claims 7-14 and 17-23 are currently pending. In addition, claims 17-23 are drawn to non-elected species and/or inventions and thus these claims remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), there being no allowable generic claim. Therefore, claims 7-14 are examined on the merits.

Those sections of Title 35, US code, not included in the instant action can be found in previous office actions.

Comments

2. Applicants state, "Regarding the Advisory Action dated December 19, 2006, it is noted that page 2 of the Action states that the amendment to claim 7 ... introduces the issue of new matter. It is respectfully submitted that deletion of this limitation is not new matter. It is believed that the intention of the Examiner was to state that the amendment introduces a new issue that requires further consideration or search." (e.g., see 1/17/07 Response, page 1). The Examiner

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agrees with this statement (i.e., the cited passage was a typographical error as stated by Applicants).

Withdrawn Objections/Rejections

3. The 35 U.S.C. § 112, second paragraph rejection denoted "A" is hereby withdrawn in view of Applicants' amendments to claim 8. The new matter rejection under 35 U.S.C. § 112, first paragraph is withdrawn in view of Applicants' amendments to claim 8. The Masquelin et al. rejection under 35 U.S.C. § 102(b) is withdrawn in view of Applicants' amendments removing the X is "optionally substituted amino" limitation. For the same reason the Noda et al. rejections under 35 U.S.C. §§ 102 and 103 are also withdrawn. All other rejections are maintained and the arguments are addressed below.

New Rejections

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 7-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

AA. ***Claims 7 and 9*** recite the limitation "the adjacent nitrogen atom" when defining R⁴ and R⁵. There is insufficient antecedent basis for this limitation in the claim.

Therefore, claims 7, 9 and all dependent claims are rejected under 35 USC 112, second

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paragraph.

BB. For *claims 7, 10, 11, 13 and 14*, the phrase “optionally substituted” is vague and indefinite with respect to ring (A) in light of the fact that A “must be” substituted (e.g., compare to claim 14 wherein Z^2 is defined as alkylene or O etc., which is not an “optional” substituent). Therefore, the claim is internally inconsistent. Applicants are requested to clarify or correct. Therefore, claims 7, 10, 11, 13, 14, and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

CC. For *claims 9-14*, the phrase “a tautomer of itself, a pharmaceutically acceptable salt thereof or a solvate thereof” is vague and indefinite in light of the fact that this limitation describes a “side chain” (e.g., see claim 9 wherein the R4/R5 combination are defined) as opposed to the “entire molecule.” Applicants are requested to clarify and/or correct. Therefore, claims 9-14 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

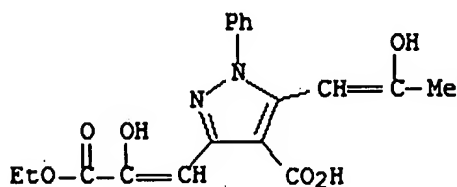
5. Claims 7, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Brbot-Saranovic et al. (Brbot-Saranovic et al., “Structure determination of some

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pyronylpyrazoles. Correction of the structures described as pyrano[4,3-c]pyrazoles”

Heterocycles **1992**, 34(8), 1547-54).

For *claims 7, 9 and 10*, Brbot-Saranovic et al. (see entire document) disclose 3-(3-ethoxy-2-hydroxyl-3-oxo-1-propenyl)-5-(2-hydroxyl-1-propenyl)-1-phenyl-1H-Pyrazole-4-carboxylic acid (e.g., see abstract, see also page 1549, compound 8, RN 126360-80-3, see also corresponding picture below), which anticipates the claimed invention. In this scenario, A is an imidazole ring substituted with phenyl and -CO₂H groups (i.e., an optionally substituted aromatic heterocycle); R¹-Z³-Z²-Z¹ is -C=C(OH)-Me (i.e., R¹ is =C(OH)-Me, which represents an optionally substituted C1 alkenyl with -OH and -Me substitutions, Z¹/Z³ = bond, Z² is -C=, which represents an optionally substituted C1 alkenylene); Z is hydrogen; X is OH; Y is -CO₂Et (i.e., -C(=R²)-R³-R⁴ wherein R²/R³ is oxygen and R⁴ is optionally substituted alkyl).



RN 126360-80-3

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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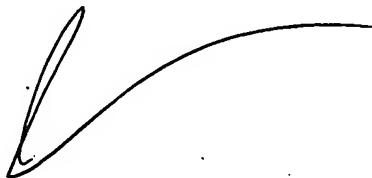
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.

March 21, 2007

JON EPPERSON
PRIMARY EXAMINER

A handwritten signature in black ink, consisting of a large, stylized 'J' followed by a long, sweeping horizontal stroke that curves slightly upwards at the end.